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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,920	03/22/2001	Sherman Fong	P1192-2	6172

9157 7590 05/20/2003
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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/20/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,920

Applicant(s)

FONG ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19, 20 and 22-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 22-26 and 32-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 19, 20, 27-31 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17, 19, 20 and 22-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 13 January 2003 (Paper No. 10) has been entered in full. Claim 21 was cancelled. Claims 15-17, 19, 20, 27-31 and 47 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Matter of Record

Applicant has recited support for claim 18 on page 4 of the amendment filed 13 January 2003 (Paper No. 10). Claim 18, however, was cancelled in the amendment filed 21 June 2002 (Paper No. 8).

Withdrawn Objections And/Or Rejections

The objection to the specification as set forth at page 2 of the previous Office Action (06 November 2002, Paper No. 9) is *withdrawn* in view of the amendment (13 January 2003, Paper No. 10).

The objection to claims 27, 29, 30 and 31 as set forth at pages 2-3 of the previous Office Action (06 November 2002, Paper No. 9) is *withdrawn* in view of the amendment (13 January 2003, Paper No. 10).

The rejection of claims 15, 17, 19, 20, 27-31 under 35 USC 102 (e) as being anticipated by Ni *et al.*, US Patent No. 5,910,431 as set forth at pages 3-4 of the previous Office Action (06 November 2002, Paper No. 9) is *withdrawn* in view of the amendment (13 January 2003, Paper No. 10).

The rejection of claim 21 under 35 USC 103(a) as being unpatentable over

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Ni *et al.*, US Patent No. 5,910,431 in view of Boyle, US Patent No. 5,843,678 as set forth at pages 4-5 of the previous Office Action (06 November 2002, Paper No. 9) is *withdrawn* in view of the amendment (13 January 2003, Paper No. 10).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-17, 19, 20, 27-31 and 47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by substantial utility

The claimed invention is not supported by a substantial utility. Example 10 teaches the stimulatory activity of the Bolekine polypeptide in a mixed lymphocyte reaction (MLR). Example 11 demonstrates that the Bolekine polypeptide stimulates an immune response and can induce inflammation at the site of injection of the animal. The claimed invention is not supported by a substantial utility because there is no information regarding the correlation of the results for mixed lymphocyte reactions (results from Example 10) to any real life diseases. The specification fails to teach where an enhancement of an immune response is beneficial and therapeutically useful. The specification does not disclose how the induction of inflammation (results from Example 11) is beneficial and therapeutically useful. There is no information regarding which subsets of immune responses, immune cell types, etc. are targeted by compounds with activities in MLR. There is no correlation to the predisposition of a particular disease and the claimed invention and/or how the results from Examples 10

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and 11 correlate to a substantial utility. Further experimentation is required before this asserted utility is substantial.

A substantial utility amounts to more than a starting point for further research and investigation. It does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be. The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed polypeptide.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
May 19, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600